

§ 73.2

HHS select agent and/or toxin means a biological agent or toxin included in § 73.3.

Overlap select agent and/or toxin means a biological agent or toxin listed in § 73.4 and 9 CFR part 121.4.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Proficiency testing means the process of determining the competency of an individual or laboratory to perform a specified test or procedure.

Responsible Official means the individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Select agent and/or toxin means unless otherwise specified, all of the biological agents or toxins listed in §§ 73.3 and 73.4.

Specimen means samples of material from humans, animals, plants or the environment or isolates or cultures from such samples for the diagnosis, verification, or proficiency testing.

State means any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means all of the States.

USDA means the United States Department of Agriculture.

Verification means the demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity)

42 CFR Ch. I (10–1–12 Edition)

specifications for any procedure used for diagnosis.

§ 73.2 Purpose and scope.

This part implements the provisions of the Public Health Security and Biodefense Preparedness and Response Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both CDC and APHIS.

§ 73.3 HHS select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety.

(b) HHS select agents and toxins:

Abrin
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Cercopithecine herpesvirus 1 (Herpes B virus)
Clostridium perfringens epsilon toxin
Coccidioides posadasii/Coccidioides immitis
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola viruses
Francisella tularensis
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin
South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
Staphylococcal enterotoxins
T-2 toxin
Tetradotoxin

Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever])

Variola major virus (Smallpox virus) and Variola minor virus (Alastrim)

Yersinia pestis

(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional form(s) of any of the toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) HHS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) HHS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any HHS select agent or toxin that is in its naturally occurring environment provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable HHS select agents or nonfunctional HHS toxins.

(3) HHS toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 100 mg of Abrin; 0.5 mg of Botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; 1,000 mg of T-2 toxin; or 100 mg of Tetrodotoxin.

(e) An attenuated strain of a HHS select agent or toxin may be excluded from the requirements of this part based upon a determination that the

attenuated strain does not pose a severe threat to public health and safety.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at <http://www.cdc.gov/>.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any HHS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to CDC or APHIS.

(i) The seizure of Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Lassa fever virus, Marburg virus, South American Haemorrhagic

§ 73.4

42 CFR Ch. I (10–1–12 Edition)

Fever virus (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 70 FR 61049, Oct. 20, 2005; 73 FR 61365, Oct. 16, 2008; 73 FR 64554, Oct. 30, 2008]

§ 73.4 Overlap select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products.

(b) Overlap select agents and toxins:

Bacillus anthracis

Brucella abortus

Brucella melitensis

Brucella suis

Burkholderia mallei (formerly *Pseudomonas mallei*)

Burkholderia pseudomallei (formerly

Pseudomonas pseudomallei)

Hendra virus

Nipah virus

Rift Valley fever virus

Venezuelan Equine Encephalitis virus

(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional form(s) of any overlap toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment provided that the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable overlap select agents or nonfunctional overlap toxins.

(e) An attenuated strain of an overlap select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety, to animal health, or to animal products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at <http://www.cdc.gov/>.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting overlap select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.